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### **REMARKS**

#### **Status of the Claims:**

With entry of the instant amendment, claims 2, 3, 5 – 13, 26 – 34, 36 and 89 – 98 are pending. Claims 2, 26, 27, 29, 36, 89 – 93 and 95 have been amended, and claims 96 – 98 are new. Claims 1, 4, 14 – 25, 35, 37 – 82, 86 and 88 have been cancelled, and claims 83 – 85 and 87 are withdrawn. Applicants assert new matter has not been introduced by the present amendment. Further Applicants retain the right to file continuation and/or divisional applications on the subject matter of any cancelled or withdrawn claim.

Claim 2, which is directed to an HAC1 protein has been amended as an independent claim incorporating most of the elements of now cancelled claim 1. More specifically, the DNA binding domain is defined as having at least 90% sequence identity to the binding domain of SEQ ID NO: 5, SEQ ID NO: 6 or SEQ ID NO: 19 (those binding domains disclosed in Figures 10 and 28). Claims previously dependent on claim 1 have been amended to depend from claim 2 and have been modified in accordance with claim 2.

New claims 96 and 97, which depend from dependent claim 95 further define the eukaryotic cell and the binding domain. New claim 98 is directed to specific promoters that may be operably linked to the nucleic acid encoding the binding domain, and support is found at page 29 and in the examples of the specification.

#### **Entry and consideration of the Information Disclosure Statement:**

The Examiner has indicated that the IDS submitted on September 15, 2003 failed to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document, each non-patent literature publication or that portion which caused it to be listed and all other information or that portion which caused it to be listed. The Examiner did not consider the IDS but merely placed it in the file.

Applicants emphasize that the present application is a continuation application of prior application serial no. 09/816,277 filed March 23, 2001, which is a continuation in part of application serial number 09/534,692 filed March 24, 2000. The IDS submitted in the present application is the same as the IDS submitted in the parent application. The references listed on Form PTO-1449 were not supplied in the present application because they were previously cited by or supplied to the Office in the parent application. Applicants respectfully contend the IDS was properly submitted in compliance with the CFR rules and further should have been

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considered by the Examiner. Applicants request that the Examiner consider the references as submitted in the IDS and indicate such by initialing Form PTO-1449.

**Objection to the Specification:**

The Examiner has objected to the specification because sequence identifiers are missing for sequences disclosed in Figure 10 and 16. The description of Figure 10 (page 10 of the disclosure) and Figure 16 (page 11 of the disclosure) has been amended to include appropriate sequence identifiers.

**Claim Objections:**

The Examiner has objected to claim 1 due to the phrase "from a yeast or a filamentous fungi". Claim 1 has been cancelled.

**Rejection under 35 U.S.C. §112, second paragraph:**

The Examiner has rejected claims 1 – 2, 4, 26 – 27, 29, 36, 88 – 90 and 95 (and claims dependent thereon) as being indefinite for failing to particularly point out and distinctively claim the subject matter which Applicants regard as the invention. Applicants believe the instant amendment renders the rejection under section 112, second paragraph moot.

Specifically, claims 1 and 4 have been cancelled. Claim 2 recites that the nucleic acid encoding a HAC1 UPR modulating protein is transformed into a eukaryotic cell and specific sequence identifiers are provided for the DNA binding domains. Claims have been amended to specifically refer to a eukaryotic cell or parent cell as appropriate. Claim 95 has been amended to recite various combinations of heterologous proteins "selected from the group consisting of".

**Rejection under 35 U.S.C. §112, first paragraph:**

The Examiner has rejected claims 1 and 88 – 90 (and therefore dependent claims 2 – 13, 26 – 34, 36 and 91 – 95) as failing to comply with the written description requirement.

Claim 1 has been cancelled. Amended claim 2 is directed to a HAC1 UPR-modulating protein comprising a DNA binding domain having at least 90% identity to a DNA binding domain of a) amino acid residues 84 – 147 of SEQ ID NO: 5; b) amino acid residues 53 – 116 of SEQ ID NO: 6, or c) amino acid residues 45 – 116 of SEQ ID NO: 19 and amended claims 88 – 90

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depend from claim 2. The rejection under section 112, first paragraph is rendered moot by the claim amendments.

**Rejection under 35 U.S.C. §102(b):**

The Examiner has rejected claims 1 – 2, 4 – 7, 26 – 28 and 88 – 90 as anticipated by Clarke et al. (J. Cell. Bioch. Suppl.) as evidenced by Shamu (Current Biology). Applicants respectfully traverse this rejection. Anticipation requires identity of the claimed process and a process of the prior art; the claimed process including each step thereof must have been described or embedded, either expressly or inherently in the cited reference and clearly the cited references of Clarke and Shamu fail this test.

Clarke teaches that “targeted disruptions of IRE1 showed reduced levels of expression” of certain proteins. Clarke further hypothesizes that “over expression or increased activity of IRE1 may result in increased expression of foreign proteins”. Clarke does not address any aspect of secretion of foreign proteins by the host cell. Furthermore, Clarke does not teach that elevating the UPR by increasing HAC1 levels will enhance secretion of heterologous proteins.

This deficiency of Clarke is not corrected by reference to Shamu. While Shamu does teach that IRE1 is involved in the splicing of HAC1 mRNA there is no indication that *secretion* of heterologous proteins would be effected by altering HAC1 levels.

There are no other cited prior art rejections.

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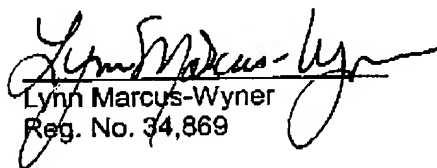
**Conclusion**

In light of the above amendments, as well as the remarks, Applicant believes the pending claims are in condition for allowance and issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 846-7620.

Respectfully submitted,

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